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09/650,005	08/28/2000	Glenn F. Osborne	25527-0005	7486

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HELLER EHRMAN WHITE & MCAULIFFE LLP  
275 MIDDLEFIELD ROAD  
MENLO PARK, CA 94025-3506

EXAMINER
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LU, TOM Y

ART UNIT	PAPER NUMBER
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2621

DATE MAILED: 09/26/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/650,005

Applicant(s)

OSBORNE ET AL.

Examiner

Tom Y Lu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 August 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group II, Claims 21-24 in Paper No. 12 is acknowledged.
2. Upon further review of specification, the examiner withdraws restriction requirement on Claims 1-20. Consequently, Claims 1-24 are pending. Claims 1-24 are examined.

### ***Claim Objections***

3. Claim 1 is objected to because of the following informalities: A typographical error is found. "Data analyses" should be changed to "data analysis" in line 5. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 2, 3, 5, 7, 14, 15, 16, 17, and 19 are rejected under 35 U.S.C. 112 2<sup>nd</sup> Paragraph.
  - a. Claim 2 recites the limitation "the group" in line 2. There is insufficient antecedent basis for this limitation in the claim.
  - b. Claims 3, 5, 7, 14-17 and 19 are rejected for the same reason given in Claim 2 above.
5. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant fails to describe "R&D". A clear explanation is required.

### ***Claim Rejections - 35 USC § 102***

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claim 1-11, 18 and 20-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Sabatini et al (U.S. Patent No. 5,966,712).

a. Referring to Claim 1, Sabatini discloses a Web server that communicates (Sabatini at column 13, line 44, discloses Web server 156 as shown in figure 2A as well) with at least one user facility (Sabatini at column 13, line 28, discloses clients 138a and 138b, see figure 2A), receiving and transmitting hybridization information (Sabatini at column 29, lines 38-41, lines 50-51, teaches using DNA or RNA probes to hybridize complementary sequence samples on the membrane, and such sequence information is stored in a data base. And such sequence information is the claimed “hybridization information” and is stored in database 144 as shown in figure 2A), supporting data analysis (Sabatini at column 29, line 66, teaches “Electronic Southern analysis”), and providing security (Sabatini in figure 2A shows firewall gateway 140, and the use of TCP protocol at column 13, line 35 to provide necessary security for communication) and business functions (Sabatini at column 13, line 39, teaches the client machines accessing a website such as Genbank, and such access service is a subscription service, which is a business function); a database server that stores hybridization profiles (Sabatini in

figure 2A shows sequence database 144 stores the hybridization information described at column 29, lines 38-41, and lines 50-51), clinical information associated with hybridization profiles (Sabatini at column 30, line 8, teaches “GI description” which corresponds to the claimed “clinical information”), and statistical information associated with hybridization profiles (Sabatini at column 30, line 7, teaches “ORF ID” as claimed “statistical information”); and an application server that facilitates information exchange between the Web server and the data server (Sabatini at column 13, line 31, discloses Web application 154 which facilitates information exchange between the Web server and the data server as shown in figure 2A).

- b. Referring to Claim 2, Sabatini discloses wherein the Web server further comprises functions selected from the group consisting of product information (DNA sequences from the organism’s genome as described at column 8, line 66, Organism ID at column 16, line 1), product ordering (client accessing is product ordering), company information (Genbank), statistical summary of patient database (Sabatini at column 16, lines 2-4, teaches “HitDataSource field which identifies the external Genbank databasesource of the HitID used to annotate an ORF in a library”, the number of hits about ORF is statistic data), request to the application server (client request from the clients 138a and 138b), and security (firewall and TCP protocol).
- c. Referring to Claim 3, Sabatini discloses wherein the database server further comprises functions selected from the group of consisting genetic pattern database

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for chip ID (OrganismID is chip ID, column 16, line 1), patient genetic pattern database (Genomic database is a patient genetic pattern database, figure 2A), and statistical data summary (HitID shows the statistical data summary, column 16, line 4).

- d. Referring to Claim 4, Sabatini discloses wherein the application server constructs at least one query for the database server, and performs at least one statistical comparison between hybridization parameters received by the Web server and hybridization parameter supplied by the database server (column 2, lines 13-20).
- e. Referring to Claim 5, Sabatini discloses wherein the application server further comprises functions selected from the group consisting of database query for chip ID genetic pattern, data query for statistical data summary, pattern match statistical processing, and results output (Sabatini at column 12, lines 45-46 teaches the application server 154 includes the executable code necessary for generation of database language statements, which implies queries are used in order to access the database. And the limitations of chip ID, statistical data summary are explained in Claim 4, pattern match statistical processing is taught at column 3, lines 5-9).
- f. Referring to Claim 6, Sabatini discloses wherein said artificial intelligence system further comprises an operation server (Sabatini teaches the clients 138a and 138b have access to GenBank database. GenBank database provides subscription services to the clients, which inherently includes an operation server).

- g. Referring to Claim 7, Sabatini discloses wherein the operation server comprises functions selected from the group consisting of order management, billing management, and order tracking (the examiner in Claim 6 explains the GenBank provides subscription services to clients, which inherently contains order management, billing management, and order tracking for the service and product it provides as every commercial website would do).
- h. Referring to Claim 8, Sabatini discloses wherein the user facility is linked to said artificial intelligence system (Sabatini at column 8, line 18 teaches such system is an automated "bioanalysis" system, which inherently implies artificial intelligence) through encrypted network connections (by applying the firewall and TCP protocol, the network connections are secure and encrypted. Note every browser, such a Netscape browser as Sabatini uses inherently contains the minimum 40-bit encryption).
- i. Referring to Claim 9, Sabatini discloses wherein the user facility is a remote user facility (Sabatini discloses the clients 138a and 138b are remote machines and connected to the servers through Internet as shown in figure 2A).
- j. Referring to Claim 10, Sabatini discloses wherein the user facility is a local user facility (Sabatini at column 12, line 13, teaches the clients can be connected through LAN).
- k. Referring to Claim 11, Sabatini discloses wherein the user facility is selected from the group consisting of a hospital, a clinic, a research facility, a business, and a

non-profit organization (Sabatini discloses a pharmaceutical research facility at column 1, line 45).

- l. Referring to Claim 18, Sabatini discloses wherein the user facility comprises a computer linked to a network; and a user interface to display data related information (Sabatini discloses where client machines 138a and 138b are computers linked through Internet).
- m. Referring to Claim 20, Sabatini discloses a system architecture based on a shared processing functionality between at least one remote location and at least one central data processing facility (see figure 2A).
- n. Referring to Claim 21, Sabatini discloses collecting hybridization information from a nucleic acid array (Sabatini at column 29, lines 52-55, teaches using a "probe" DNA sequence, and such probe as Sabatini described at column 29, lines 38-39, contains hybridization information); transmitting said hybridization information to a central data processing facility (Sabatini at column 30, line 2 discloses accessing external database such as GenBank, which contains a database as shown in figure 2A), analyzing said hybridization information to generate a hybridization profile (Sabatini at column 29, line 60, teaches performing Electronic Southern analysis, which analyze the probe DNA sequence and generates a query to match the sequence in the database. Note such query is generated based on the probe DNA sequence, and the probe DNA sequence contains hybridization information. Therefore, the query herein corresponds to the claimed "hybridization profile"); comparing said hybridization profile to stored



hybridization parameters to provide analyze data (Sabatini at column 30, lines 1-12, teaches using the query contains hybridization information to match the same sequence in GenBank database. The analyzed data is the matched result as described at column 30, line 58); and determining the physiological condition suggested by said analyzed data through the use of artificial intelligence (Sabatini at column 31, lines 6-7, teaches from the output result, the user can determine which organism like harbor genes similar to those he or she is investigating. With regard to use of artificial intelligence, Sabatini at column 8, line 18, discloses it is an automated “bioanalysis system”).

- o. Referring to Claim 22, Sabatini discloses recommending methods of treatment based on the physiological condition (Sabatini at column 16, lines 2-4, discloses corresponding physical data model table 302 includes an HitDataSource field which identifies the GenBank database source of the HitID used to annotate an ORF in a library, such annotation as Sabatini defines at column 6, line 41, contains Medline reference, which is considered as a form of recommending methods of treatment).
- p. With regard to Claim 23, the only difference between Claim 23 and Claim 21 is Claim 23 calls for a proteomics chip, which will generate a proteomics profile, and the database stores proteomics parameters. Sabatini at column 6, lines 16-17 points out the coding sequence is a protein sequence. Therefore, “probe’ sequence at column 29, line 38 is also referring to a protein sequence. GenBank database can be a protein sequence database as described at column 6, line 51 and column

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9, line 65. According to the specification, page 9, lines 15-16, the term "proteomics" is broadly defined as the systematic analysis and documentation of proteins in biological samples. Therefore, Sabatini teaches a proteomics chip at column 36-37, and the later generated profile is proteomics profile. All other limitations are addressed in Claim 21.

q. With regard to Claim 24, the limitation is addressed in Claim 22.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 12-17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sabatini in view of Lipshutz et al (U.S. Patent No. 5,733,729).

a. Referring to Claim 12, Sabatini discloses obtaining hybridization information, and a computer linked to a network; a user interface to display data related information. However, Sabatini does not disclose an optical scanning system, and an image processing system. Lipshutz at column 5, lines 32-36, discloses an optical scanning system and an image processing system to obtain hybridization information. At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to include an optical scanning system, and an image processing system. One of ordinary skill in the art would have been motivated to do this because Sabatini at column 29, lines 38-42 teaches obtaining the hybridization information of an organism and analyzing such

information by using GenBank database. Lipshutz discloses using an optical scanning system, and an imaging processing system to obtain the hybridization information, and performing the analysis by using GenBank database as well. The only difference between Sabatini and Lipshutz is Lipshutz provides means of obtaining the hybridization information. It is reasonable to assume a person of ordinary skill in the art would apply the means taught by Lipshutz to obtain hybridization information.

- b. Referring to Claim 13, Sabatini discloses wherein the network is the Internet (see figure 2A).
- c. Referring to Claim 14, Sabatini discloses wherein the user interface further comprise functions selected from the group of consisting of manipulating data, searching data, analyzing data, and displaying data (column 29, lines 58-67, column 30, lines 1-12).
- d. Referring to Claim 15, Sabatini discloses displayed information selected from the group consisting of user information (Sabatini teaches client accessing, therefore, user information is inherently included), clinical sample information (Sabatini at column 16, line 1, teaches organismID), testing information (Sabatini teaches it is a genetic matching, therefore it is a genetic testing), clinical test results report (Sabatini at column 30, line 8, teaches GI description), R&D sample information (Sabatini at column 30, line 7, teaches ORF ID), therapeutic choice (Sabatini at column 30, line 9, teaches providing annotation of a sequence, and such annotation described at column 6, line 40. include Medline reference), and billing information (Sabatini teaches GenBank provides access for clients, therefore, the billing formation is inherent). Since Lipshutz provides means for obtaining the hybridization information, Lipshutz teaches chip information (Lipshutz:

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column 5, line 52) and result report for biopharma chip (Lipshutz at column 5, lines 54-55, teaches identifying whether specific mutations in a receptor such as DNA or RNA).

- e. Referring to Claim 16, Sabatini discloses wherein the data related information is selected from the group consisting of hybridization information (Sabatini: probe sequence), patient information (Sabatini: organismID), statistical information (Sabatini: number of hits about ORF, column 16, lines 2-4), clinical information (organismID), medical information (GI description), diagnosis information (GI description), treatment information (GI description), biological information (organismID), product information (organismID), and company information (GenBank).
- f. With regard to Claim 17, all limitations are addressed in Claim 3.
- g. With regard to Claim 19, all the limitations are addressed in Claim 16.

### ***Conclusion***

- 8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Zheng et al, U.S. Patent No. 6,263,287 B1, see column 2.

- 9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tom Y Lu whose telephone number is (703) 306-4057. The examiner can normally be reached on 8:30AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Leo H Boudreau can be reached on (703) 305-4706. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3900.

Tom Y. Lu

  
DANIEL MARIAM  
PRIMARY EXAMINER